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The British Pharmacopoeia (BP) is a comprehensive guide for pharmaceutical substances and medicinal products. It includes official standards from the European Pharmacopoeia, as well as UK-specific national standards. This resource aims to help users understand the requirements and contents of the BP, including where to find specific information. To ensure compliance with BP standards, drug products must meet requirements throughout their shelf life, regardless of whether they claim compliance or not. All ingredients used in a product must comply with published BP or Ph. Eur. monographs for those substances. The product must also meet relevant general monograph and formulated preparation monograph requirements. If you've developed an improved method or believe there's an error in the BP, contact bpcom@mhra.gov.uk to contribute to monograph development or report errors with supporting data. The BP is organized into different sections, including: * Preliminaries: informative texts, including the Introduction and updates on high-profile activities * General Notices: essential reading for understanding mandatory and non-mandatory statements, terms definitions, and more * Monographs: Medicinal and Pharmaceutical Substances (Volumes I and II) Monographs contain guidelines for pharmaceutical ingredients and excipients. General monographs apply to all products, while specific monographs cover unique formulations like small molecule or biological medicines. These are found in Volume III of the hard copy. For more detailed information on a formulation BP monograph, refer to the next section of this guide. Herbal drugs and homoeopathics, blood-related products, immunological products, vaccines, radiopharmaceuticals, and surgical materials can be found in their respective sections of Volume IV. Infrared reference spectra are linked within formulated preparation monographs (Volume V). Determining concordance is explained in the General Notices. The Appendices contain methods for analysis, container texts, reagent preparation, and most general texts related to Ph. Eur. section 5. When an appendix is referenced, its requirements apply unless stated otherwise. Supplementary Chapters provide non-mandatory information. For advice on tests or calculations in BP, these chapters may have the necessary information (Volume V). The British Pharmacopoeia (Veterinary) contains sections for veterinary medicines (Volume VI). The techniques employed should adhere to the specifications outlined in relevant appendices, such as Appendix III Chromatographic Separation Techniques and Appendix III D Liquid Chromatography when utilizing LC. Appendices form part of the official requirements for BP monographs. Supplementary Chapters provide explanatory texts intended to aid users; however, it is crucial to confirm that the methods are suitable for the specific drug product being tested, taking into account factors like excipients that may affect analysis. Aspirin serves as the British Approved Name (BAN) for acetylsalicylic acid in the UK. The General Notices offer valuable information on using BP monographs, emphasizing compliance with monograph requirements, highlighting mandatory and advisory sections, and permitting alternative tests to those described. Advisory information typically accompanies common indication(s), usually aligned with BAN publication entries. The drug substance used to manufacture tablets must comply with relevant Ph Eur or BP monographs for that substance. In this case, the Aspirin monograph (Ph. Eur. monograph 0309, Acetylsalicylic Acid) applies. Tablets must conform to the Tablets general monograph and contain 95.0 to 105.0% of the stated amount on the label. When applied within a quality framework for medicinal products, BP monographs are designed to ensure that drug products comply with requirements, including identification tests. Italicized text refers users to corresponding BP sections or appendix entries. The tests in this section determine product quality attributes; the product must meet test requirements. Alternative methods can be used if they demonstrate equivalent measures of the requirement, as stated in General Notices Part II's 'Assays and Tests' section. Q value limits apply Monographs published before BP 2008 do not follow Appendix XII B requirements; instead, The British Pharmacopoeia's monograph rules apply, as listed in SC I E Dissolution Testing of Solid Oral Dosage Forms. Monographs released in BP 2008 or later must comply with Appendix XII B. They include dissolution and Q value limits within the monograph itself. If a monograph doesn't have a 'Limits' section after 'Determination of content', check SC I E's section 3.4 for details. If the title is listed there, apply a limit not less than 70% of the label claim in 45 minutes. Otherwise, follow the decision tree in SC I E's section 3.3. This test primarily focuses on potential impurities related to the drug substance rather than all possible contaminants or adulterants. Appendix III Chromatographic Separation Techniques provides guidance on adjusting chromatographic conditions, including details about the column brand used when the method was established. General Notices require that assays and tests are performed between 15 to 25 °C unless stated otherwise. The system suitability requirement does not strictly need an exactly 5-minute retention time if impurities can be detected/identified; variation in equipment and columns is expected. For example test results, check the online BP's More Resources section. Appendix III gives details on how to measure resolution. Guidance on controlling impurities and calculating limits can be found in SC I A and SC VI A. The limit is measured against the peak area of solution (3), which is typically a dilution of the test solution or an external standard of the impurity. The figure '3%' indicates the limit as a percentage relative to Aspirin in the test solution, but it's not a numerical limit; if given, it will appear without parenthesis. Secondary peaks exclude drug substance(s), reagents, internal standards, and derivatising agents; those due to mobile phase, sample matrix, excipients, and counter-ions can also be disregarded. Substance peak in chromatogram must not exceed certain limits, apart from specified impurities. Secondary peaks are addressed in Appendix III and do not include impurities with specific limits. The limit can be the sum of any secondary peaks or areas, excluding those with specific limits. If there is a peak corresponding to impurity C, it should not be included in the sum. The disregard limit is based on maximum daily dose for drug substance and ICH guidelines. The declared content of BPCRS is available online and in leaflet, while labelling requirements are limited to monographs and must meet regulatory authority standards. The Related substances test detects impurities listed in Aspirin (Ph. Eur.) monograph. Aspirin Tablets comply with requirements for tablets and stated amount of aspirin. The content of aspirin is determined by infrared absorption spectrum of residue, which is concordant with reference spectrum of aspirin. Test conditions include apparatus 1 rotating basket at 50 rpm and pH 4.5 buffer medium prepared from sodium acetate, glacial acetic acid, and water. Procedure involves withdrawing a sample after 45 minutes, measuring absorbance at 265 nm, and calculating total content using declared content of C9H8O4 in aspirin BPCRS. Chromatographic conditions include stainless steel column (25 cm x 4.6 mm), mobile phase composed of water and acetonitrile, and flow rate of 1 mL/minute. Use HPLC system with octadecylsilyl silica gel column (5 µm). Mobile phase: mix orthophosphoric acid, acetonitrile, and water in specific volumes. Set flow rate to 1 mL/min and ambient column temperature. Detect at 237 nm wavelength. Inject 20 µL of each solution and allow chromatography to run for 8 minutes (retention time of impurity F). Validate system by checking resolution between aspirin and impurity C peaks. Chromatogram results: impurities A, B, and C should have retention times around 0.6-1.4 minutes relative to aspirin (5-minute retention time). Impurity F has a longer retention time of about 8 minutes. System suitability requires resolution between aspirin and impurity C peaks to be at least 6. Limit impurities in tablets: any peak corresponding to impurity C should not exceed 3% of the principal peak area, while other secondary peaks should be less than half or 0.1% respectively. Total area of secondary peaks should be within 1%. Disregard peaks with areas less than 0.05% of the principal peak. Follow HPLC conditions under Related substances for chromatographic procedure and system suitability validation. Calculate C 9H 8O 4 content in tablets from chromatograms, using declared content of aspirin as reference.